

REMARKS

I. Amendments to the Claims:

Claims 29-33, 36-42, 45, 47-50, 80-82, 92-100 and 102-103 were pending in this application. Claims 34, 43, 46, 51, 53-59, 61-68, 70-78, 84-86, 91, and 101 were withdrawn as being drawn to a non-elected invention.

Claims 29, 99, 100, and 103 have been currently amended. Support for the claim amendments can be found throughout the application as filed. Accordingly, no new matter has been added.

Claim 102 has been canceled without prejudice. Applicant reserves the right to pursue the subject matter of this claim in a future related application.

Upon entry of the instant amendments to the claims, claims 29-33, 36-42, 45, 47-50, 80-82, 92-100 and 103 will be pending and under examination in the instant application.

II. Rejection Under 35 U.S.C. § 112, First Paragraph, Enablement:

Claim 102 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. (*see*, Office Action, page 3).

Without acquiescing to this rejection, and solely with a view towards expediting prosecution of this application, Applicant has canceled claim 102 herewith.

In view of the instant amendment to the claims, Applicant respectfully submits that grounds for this rejection have been rendered moot. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

III. Rejection Under 35 U.S.C. § 102(b):

Claims 29-33, 36-42, 45, 47-50, 90, and 92-100, and 102-103 were rejected under 35 U.S.C. § 102(b) as purportedly being anticipated by Ghalie *et al.*, *Am. J. Hematol.*, 42:350-353, 1993 as evidenced by Mardiney, III *et al.* (U.S. 6,103,694). (*see*, Office Action, page 5).

The Office Action alleges that the teachings of Ghalie *et al.* meet every limitation of the claims. Applicant respectfully traverses this rejection for the following reason.

For a reference to anticipate a claimed invention in terms of 35 U.S.C. § 102, the prior art must teach *each and every element* of the claimed invention. *Lewmar Marine v. Barent*, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987).

The independent claims as amended (pursuant to the Examiner's suggestion; *see*, Office Action, page 7, last sentence) are directed to methods for treating or alleviating symptoms of an autoimmune disease in a patient having or suffering an autoimmune disease. The treatment recited in the claims lead the patient to have an improved prognosis for the autoimmune disease compared to an untreated patient suffering from the autoimmune disease.

Ghalie is directed to the use of a synthetic analog of Gn-RH (leuprolide) to prevent heavy menstrual bleeding that occurs in pre-menopausal women undergoing bone marrow transplantation. The procedure involves a pretransplantation preparative regimen of total-body irradiation and cyclophosphamide or high-dose combination chemotherapy, administration of leuprolide at least 1 month before admission for BMT, followed by BMT. There is simply no teaching or suggestion in Ghalie of a method for treating or alleviating symptoms of an autoimmune disease in a patient having or suffering an autoimmune disease, wherein the treatment leads "the patient to have an improved prognosis for the autoimmune disease compared to an untreated patient suffering from the autoimmune disease."

Because Ghalie does not teach each and every limitation of the claimed invention, Applicant submits that Ghalie does not anticipate Applicant's claimed invention. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection under 35 U.S.C. § 102(b).

IV. Rejections Under 35 U.S.C. § 103(a):

(a) Claims 29, 80, and 82 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Ghalie *et al.*, *Am. J. Hematol.*, 42:350-353, 1993 in view of Mardiney, III *et al.* (U.S. 6,103,694). (*see*, Office Action, page 7).

According to MPEP § 2143, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the

references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As discussed above with respect to the § 102 rejection above, Ghalie *et al.* do not teach or suggest all the limitations of Applicant's independent claims as amended. The secondary reference, Mardiney, which has been used by the Office Action for teaching methods of administering certain cytokines to patients for engrafting hematopoietic pluripotent cells, does not remedy the deficiencies of Ghalie *et al.* outlined above as it also does not teach a method for treating or alleviating symptoms of an autoimmune disease in a patient having or suffering an autoimmune disease.

Applicant notes that the instant claims as amended are not directed to improving engraftment after bone marrow transplantation (BMT), but rather to a method for treating or alleviating symptoms of an autoimmune disease in a patient having or suffering an autoimmune disease. Because the combined references do not teach all claim limitations, Applicant respectfully submits that the grounds for this rejection have been overcome. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

(b) Claim 81 remains rejected as purportedly being obvious over Ghalie *et al.*, *Am. J. Hematol.*, 42:350-353, 1993 in view of Mardiney, III *et al.* (U.S. 6,103,694) and further in view of Bolotin (*Blood* 88:1887-94, 1996). (see, Office Action, page 10).

As discussed above with respect to the § 102 rejection above, Ghalie *et al.* do not teach or suggest all the limitations of Applicant's independent claims, as amended. The secondary reference, Mardiney, which has been used by the Office Action for teaching methods of

administering certain cytokines to patients for engrafting hematopoietic pluripotent cells, also does not remedy the deficiencies of Ghalie *et al.* outlined above.

The Office Action relies on Bolotin to teach the use of IL-7. However, Bolotin is directed to using IL-7 to promote thymic reconstitution and enhance thymopoiesis after bone marrow transplantation (BMT) to prevent post-BMT immune deficiency. There is no teaching in Bolotin that remedies the deficiencies of the primary and secondary reference, either alone, or in combination.

Applicant notes that the instant claims as amended are not directed to improving engraftment after bone marrow transplantation (BMT), but rather to a method for treating or alleviating symptoms of an autoimmune disease in a patient having or suffering an autoimmune disease. One with ordinary skill in the art would not consider these references to be applicable in treating or alleviating autoimmune disease in patients.

Because the combined references do not teach or suggest all claim limitations, Applicant respectfully submits that the grounds for this rejection have been overcome. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

(c) Claim 82 stands rejected as purportedly being obvious over Ghalie *et al.*, *Am. J. Hematol.*, 42:350-353, 1993 in view of Mardiney, III *et al.* (U.S. 6,103,694) and further in view of Tian (*Stem Cells* 16:193-99, 1998). (see, Office Action, page 12).

As discussed above with respect to the § 102 rejection above, Ghalie *et al.* do not teach or suggest all the limitations of Applicant's independent claims. The secondary reference, Mardiney, which has been used by the Office Action for teaching methods of administering certain cytokines to patients for engrafting hematopoietic pluripotent cells, also does not remedy the deficiencies of Ghalie *et al.* outlined above.

The Office Action relies on Tian to teach that growth hormone promotes hematopoietic reconstitution after syngeneic BMT and to accelerate hematopoiesis after autologous BMT. Tian does not remedy the deficiencies of the primary and secondary reference, either alone or in combination.

Applicant notes that the instant claims as amended are not directed to improving engraftment after bone marrow transplantation (BMT), but rather to a method for treating or alleviating symptoms of an autoimmune disease in a patient having or suffering an autoimmune disease. Because the combined references do not teach or suggest all claim limitations, Applicant respectfully submits that the grounds for this rejection have been overcome. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

V. Provisional Obviousness-Type Double Patenting Rejections:

(a) Claims 29-33, 36-42, 45, 47-50, 80-82, and 92-100 stand provisionally rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 19-26, 28-40, 55-66, 69-72, and 74-75 of U.S. Appl. 10/749,119 (*see, Office Action, page 14*).

The currently amended claims of the instant application are generally directed to methods for treating or alleviating symptoms of an autoimmune disease in a patient having or suffering an autoimmune disease and methods for reducing the risk of developing an autoimmune disease in a patient at risk of having or suffering an autoimmune disease.

Claims 19-26, 28-40, 55-66, 69-72, and 74-75 of U.S. Appl. 10/749,119 are directed to methods for inducing tolerance in a patient to a graft from a mismatched donor. These claims do not in any way teach, suggest or motivate one of ordinary skill to arrive at the currently amended claims of the instant application.

Accordingly, Applicant respectfully requests that this rejection under the judicially created doctrine of obviousness type double patenting be reconsidered and withdrawn.

(b) Claims 29 and 99-100 were provisionally rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 26, 30, and 79 of U.S. Appl. 10/749,122 (*see, Office Action, page 16*).

As noted above, the currently amended claims of the instant application are generally directed to methods for treating or alleviating symptoms of an autoimmune disease in a patient

having or suffering an autoimmune disease and methods for reducing the risk of developing an autoimmune disease in a patient at risk of having or suffering an autoimmune disease.

Applicant notes that claims 30 of U.S. Appl. No. 10/749,122 was withdrawn as being drawn to a non-elected invention, and claim 79 of U.S. Appl. No. 10/749,122 was canceled. Claim 26 of U.S. Appl. No. 10/749,122 is drawn to a method for preventing or treating disease in a patient, comprising reactivating the thymus of the patient. There is no teaching, suggestion, or motivation from claim 26 of U.S. Appl. No. 10/749,122 to arrive at methods for treating or alleviating symptoms of an autoimmune disease in a patient having or suffering an autoimmune disease and methods for reducing the risk of developing an autoimmune disease in a patient at risk of having or suffering an autoimmune disease as claimed in the instant application.

Accordingly, Applicant respectfully requests that this rejection under the judicially created doctrine of obviousness type double patenting be reconsidered and withdrawn.

CONCLUSION

Upon entry of the instant amendments to the claims, claims 29-33, 36-42, 45, 47-50, 80-82, 92-100 and 103 will be pending in the instant application. Applicant avers that the claims are in condition for allowance and respectfully request that a Notice of Allowance be issued.

Other than the fees associated with the filing of the RCE, no additional fees are believed to be due in connection with this correspondence; however, if any fees are due, please charge the requisite payment to our Deposit Account No. 08-0219.

If a telephonic interview would advance prosecution of the application, the Examiner is invited to telephone the undersigned at the telephone number given below.

Respectfully submitted,

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Ann-Louise Kerner
Ann-Louise Kerner, Ph.D.
Reg. No. 33,523

WILMER CUTLER PICKERING HALE AND DORR LLP
60 State Street
Boston, MA 02109
Tel.: (617) 526-6192
Fax: (617) 526-5000